FDA Webinar: Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time you may press star 1 on your phone to ask a question. I would like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time. I would like now like to turn the conference over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. Manufacturers of certain devices during a public health emergency are required to notify the FDA of an interruption or permanent discontinuing in the manufacturing of certain devices by Section 506J of the FDAC Act. On May 6, 2020 the FDA issued the guidance notifying CDRH of permanent discontinuing or interruption in manufacturing of device under Section 506J of the FDAC Act during the COVID-19 public health emergency.

Today Katie O'Callaghan, Deputy Director of the Division of All Hazards Response, Science and Strategic Partnerships in the Office of Strategic

Partnerships and Technology Innovation here at CDRH will present an overview of the guidance documents. She's joined by other members of CDRH.

Following the presentation we will open up the line for your questions related to information provided through the presentation. Now I give you Katie.

Katie O'Callaghan: Thank you Irene and thank you everyone for joining us today. Next slide please, Irene. So in today's webinar we will provide a few minutes of background on CDRH's role in the COVID-19 public health emergency and then get an overview of the guidance that Irene spoke to, as well as some time for questions and answers. Next slide please.

So as is the case with many of your organizations, CDRH within FDA has been working very hard to do what we can during the COVID-19 public health emergency for medical devices. The COVID-19 pandemic triggered an unprecedented increased demand of certain devices along with significant disruption to the global medical device manufacturing and supply chain operations.

We have taken many actions to help ensure that patients and healthcare providers continue to have timely access to high quality medical devices that are needed, particularly to effectively respond to the COVID-19 pandemic. This includes emergency use authorizations or EUAs, as well as other immediately in effect guidance, to help expand the ability and capability of a large number of diagnostic and serology tests, PPE, ventilators and other devices used in the treatment of COVID-19.

This also includes communication to healthcare providers on conservation strategies, as well as frequently asked questions and other communication

resources for the broader public regarding medical devices that are used during this public health emergency. Taken together, these actions provide what we consider to be the maximum appropriate regulatory flexibility to help healthcare providers, industry and the public. Next slide please.

In addition to these regulatory and communication actions, what may not be widely known to all of our stakeholders is the collaborative work that we do in partnership with you as well as other members of our stakeholder community to identify, assess, prevent and mitigate medical device shortages and their negative impacts on patients or healthcare providers for the healthcare sector. So, in doing this work we really rely on partnership from manufacturers, the healthcare sector, professional societies, international regulatory partners and a network of partners across U.S. government and foreign governments, public health entities, supply chain entities and of course researchers and innovators. Next slide please.

On March 27, 2020 the Coronavirus Aid Relief and Economic Security Act, also known as the CARES Act, was signed into law and this added Section 506J to the FD&C Act which relates to current and potential medical device shortages during the COVID-19 public health emergency. This new section, Section 506J, requires manufacturers to notify FDA of a permanent discontinuance or interruption in the manufacturing of certain devices, particularly those that are likely to lead to a meaningful disruption of supply of that device in the United States.

This information is really critical to the work that I mentioned earlier that FDA does in collaboration with manufacturers and others to prevent and mitigate shortages, particularly during the COVID-19 public health emergency. These notifications are required “during, or in advance of, a public health emergency declared by the Secretary under Section 319 of the

Public Health Service Act. Next slide.

So as Irene mentioned, we issued guidance last week to implement Section 506J of the act during the COVID-19 public health emergency. This guidance is also intended to assist manufacturers in providing FDA timely and informative notifications about such changes. It also includes recommendations about who must notify FDA, what information to include and how to notify us. And this guidance is immediately in effect and is intended to remain in effect only for the duration of the public health emergency related to COVID-19. Next slide please.

So, who must notify FDA? Section 506J(a)(1) and (2) require manufacturers of devices that are critical to public health during the public health emergency, or for which the FDA determines information on potentially meaningful supply disruption is needed during the public health emergency, must notify the FDA of an interruption or permanent discontinuance in manufacturing of such devices. Next slide please.

To implement that, the guidance outlines some recommendations for medical device manufacturers to evaluate whether or not this requirement applies to you. We outlined the following circumstances: Whether the device or accessories are life-supporting, life-sustaining or intended for use in emergency medical care, ***or*** intended for use during surgery, ***or*** used to diagnose, cure, treat, mitigate or prevent COVID-19, ***or*** would be in higher-than-typical demand during the response to the COVID-19 pandemic compared to a similar period of time. Next slide please.

There are some nuances which are expanded upon in the guidance. Does the Section 506J notification requirement apply to me? Those that ***are*** subject to 506J notification requirements include manufacturers who make a device that

is described in Section 506J(a)(1) and (2), ***and*** who hold a marketing authorization from FDA or are listed under Section 510(j) of the Act. Those devices would be subject to the notification requirement. Manufacturers of devices where the device would be one that would require a pre-market notification or prior marketing authorization from the FDA but do not have such clearance and are distributing the device exclusively in light of a FDA guidance on enforcement discretion during the COVID-19 public health emergency are ***not*** subject to the notification requirements of Section 506J. Next slide.

When must the notification be sent to FDA? Device manufacturers must notify FDA at least six months before the date of the discontinuance or interruption. Or if that's not possible as soon as is practicable and we interpret that – during the COVID-19 pandemic – as soon as is practicable to mean no later than seven calendar days after the discontinuance or interruption occurred. And after the initial notification we recommend updates every two weeks, including expected timeline for recovery, until the shortage risk has been resolved. And this is important so that we can continue to act on the most current information. Next slide please.

Next slide please. There we go. So what information to include? I would refer you to Section IV of the guidance which does include an example of recommended information to include. We hope this is helpful as manufacturers are putting together their information in their notifications. This includes the reason for discontinuance or interruption in manufacturing, some identifying information such as manufacturer name and device name, et cetera, as well as some additional information such as queries that are specific to COVID-19, additional information that could be provided on potential mitigations to any shortages, including how a FDA can help, how we could help address and alleviate shortages or other availability concerns.

As I mentioned earlier in the presentation, a lot of the work that we do in addition to regulatory action includes what we can do in partnership or collaboration with other entities. So this information, when provided, is very helpful for us to be able to use our full toolbox to prevent or mitigate shortages. It also requests production and distribution numbers which can also be very helpful to us. And any information that is provided which is trade secret or confidential will be treated as such, consistent with all of our usual laws. Next slide please.

And please send your notifications to the email box listed here, CDRHManufacturerShortage@fda.hhs.gov. And for notification please include the word "notification" in the subject line to expedite our response. Next slide please.

So in summary, the new section 506J of the Act requires manufacturers of certain devices to notify the FDA of an interruption or a permanent discontinuance in manufacturing of those devices. This immediately in effect guidance implements this section and clarifies to manufacturers what to do during the COVID-19 public health emergency. This information is truly critical to help us assess, prevent and mitigate shortages during this public health emergency. And with that I will conclude the overview and thank you for your attention. I believe we will switch gears now to questions.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question please press star 1, unmute your phone and record your name clearly. Your name is required to introduce your question. If you need to withdraw your question, press star 2. Again to ask a question please press star 1. And we'll take a few moments for questions to come through. Please stand by.

Our first question...

(Jessica Ritsick): So before we get into the Q&A portion we did just want to note that we cannot answer questions during this webinar about specific devices. So if you do have a question about your specific device, up on the screen is our mailbox address which I'm sure you'll all become very familiar with. Please use that mailbox and mark your subject line as question at the beginning and that will help us get back to you as quickly as possible. Thank you.

Coordinator: Thank you. Our first question will come from (Jeffrey Brazon). Your line is open.

(Jeffrey Brazon): Hello. Can you hear me okay? Okay my first question is - okay great. My first question is in terms of the supply chain entity piece. Can you describe who are the entities you work with and what that might look like in practice in terms of a partnership with them?

(Linda Ricci): Sure. This is (Linda Ricci). The supply chain entities we work with include not only our own Med Sun hospitals that we can have discussions with but also group purchasing organizations, other of our several partners such as entities at HHS including ASPR, as well as specific hospitals that we might have other contacts with or our network of experts, just a lot of different people that are involved not only in the manufacture or the transportation or the purchasing of devices but also in the use of the device.

(Jeffrey Brazon): Okay. And then second question if that's okay, do you work with supply chain entities related to components in raw materials by any chance?

(Linda Ricci): We have established relationships with other entities within the supply chain.

(Jeffrey Brazon): Okay, great. Thanks so much.

Coordinator: Thank you. Our next question will come from (Unintelligible). Your line is open.

Woman: Hello, thank you. So I had a question regarding meaningful disruption and reasonable period of time. I wonder if you might consider elaborate as to - what exactly is meaningful? What is reasonable period of time?

Katie O'Callaghan: I believe in the guidance we identify, for the duration of the COVID-19 public health emergency, a reasonable period of time to be one month.

Woman: Thank you.

Coordinator: Thank you. Our next question will come from (David Chadwick). You may go ahead.

(David Chadwick): Yes. Good afternoon and thank you for that nice presentation. I have two questions. The first one is if we reply to the website for shortages is that the same impact on the agency as going through the document now center or is this a different mechanism and just the data, the submission will be put in?

(Linda Ricci): Hello this is (Linda) again. So hopefully my audio is a little better now. This is a different type of submission for the notification and we are requesting that you send it through the mailbox that is highlighted on the screen right now. Other medical device submissions certainly go through the DCC, the document control center when you have obviously other types of information that you're sending into the agency for review or for information and purposes.

For the purpose of shortage notification we really would like for you to send the information into this mailbox that's highlighted on the screen.

(David Chadwick): Okay thanks (Linda). My other question deals with 506J of the CARES Act. And I thought - and I didn't really hear it emphasized within this webinar that there has to be a declared public emergency which we currently have, and that there are specific devices that FDA would be detailing as presumed in some notification beyond what the suggestions are in the CARES Act related specifically to COVID and just from my own information. I kind of thought the ebola publication was still open. So is this COVID-19 specific or is it farther reaching?

Katie O'Callaghan: So this guidance is specific to the COVID-19 public health emergency and it implements 506J for the duration of the COVID-19 public health emergency. As far as your question or comment about the specific devices because of the unprecedented scope of the impact of the COVID-19 pandemic rather than enumerate specific devices we laid out those four circumstances which I provided an overview, and you can find in Section III of the guidance, Section III.A. Any device that would meet any of those four circumstances are ones for which manufacturers should submit notification to FDA.

(David Chadwick): Thank you.

Katie O'Callaghan: Thank you.

Coordinator: Our next question will come from (Jessica Smith). You may go ahead.

(Jessica Smith): Thank you. I had a couple quick questions. One was with regard to back

orders. I understand that if you look at the reasons for the discontinuation or interruption in Section III of the guidance it includes back order as one of the possible reasons for that. The question is at what point is it left up to the manufacturer to determine when a back order is actually creating an issue in the marketplace because obviously with an increased demand, back orders could get worse. It may be two weeks. It may be six months. it doesn't seem to have very clear guidance for how far back, for example, a back order might actually qualify for an actual shortage or interruption?

Katie O'Callaghan: Yes thank you for the question. The guidance does - I'll just clarify a couple of points from the guidance. One is that the reasonable period of time for a meaningful disruption that would qualify for notification as one month. And the other point of clarification is that although we are aware that manufacturers might have some additional information that you use for business decisions in terms of what else is happening in the market, because everything is so dynamic at the moment in particular, manufacturers should really make their assessment based on their own capacities rather than looking to make projections or estimations of the overall market impacts. So hopefully that clarifies.

(Jessica Smith): Yes. It sounds like there's a little bit of - it leaves room for the manufacturer to actually make that decision based on whatever justification they need to use to determine whether or not it's actually an actual, something that's reportable is what I'm hearing. Is that consistent with what you just stated?

Katie O'Callaghan: So manufacturers will make an assessment and the guidance includes recommendations for things to consider in doing that. It sounds like you may have a more specific question about your particular circumstance, we can certainly take that offline if you want to contact us at that mailbox and include question in your subject line, we can do that quickly. Thank you.

(Jessica Smith): Okay, yes.

Coordinator: Thank you. Our next question will come from (Elizabeth George). Your line is open.

(Elizabeth George): Hello (Linda) and Katie. Thank you for this update today. I did have a question that kind of went off of what was asked earlier about the 506J with clearing the emergency in a specific product. The question I have is that if a manufacturer makes say, three different models of a particular device that falls into that category and say, one of those devices has a significant shortage either because of back orders or a product or because it seems to have a higher need,but the other two versions of the product, maybe a model version could be as an alternative. Is the expectation that the manufacturer would then report even though they have alternative options that might be suffice to fulfill the need? And I think almost any of the different products, there could be whether it be an ultrasound product or defib or something like that that falls into meeting the definition as defined in your process, but we may have multiple versions of that model, of that product.

Katie O'Callaghan: Yes, thanks (Elizabeth). Great question. The answer is yes, you would still notify us and the reason for that is particularly with some of the examples you raised where this is – potentially we're talking about capital equipment in the hospital – although there may be alternatives there may still be a short to mid-term impact on healthcare facilities for example. And so in that notification it would be wonderful if you could connect those dots and say we have these other models where we are not experiencing a shortage and that would be really helpful for us as we put the picture together in terms of what the mitigation might be or where we would need to direct our focus.

(Elizabeth George): And that would also apply then for any accessories or supplies that might be utilized to support those devices as well.

Katie O'Callaghan: Yes, particularly with proprietary accessories that are used for specific models.

(Elizabeth George): Okay thank you. I did have one additional question and I know we asked it before, is that I know that there was a comment again regarding back orders and all of that and increased production rates and things like that. I know a lot of people still are wrestling with what constitutes the shortage and when do they feel that it would justify coming to you guys to notify. And I know you gave us last week a bit of an answer on that and I thought it might be valuable to have it shared again today.

Katie O'Callaghan: Sure, thank you. As is outlined in the guidance and for the duration of COVID-19 public health emergency we're talking about shortage as any time during which demand exceeds supply. So that could be as a result of supply side disruption or increased demand or a combination of both. I think what we have tried to help manufacturers think through with the guidance – in particular Section IV which is an example of the kinds of information that you could include – is what are some of the underlying reasons or indicators of discontinuance or interruption. And some indicators are ones that have been mentioned like the product is on back order. If demand currently exceeds supply or projected demand exceeds projected supply based on your historical ordering and production numbers, those would be indicators. If the product is on allocation or there are other supply side disruptions – any of those that could contribute to a meaningful disruption - we would recommend that you consider those as triggers for notifying FDA.

Coordinator: Thank you. Our next question...

Linda Ricci: Just to add a one more quick thing to that, we would expect that you would provide that notification within seven days as indicated in the guidance. It says as soon as practicable which for this circumstance we are saying that's seven days.

Coordinator: Thank you. Our next question will come from (Michael Patrini). Your line is open.

(Michael Patrini): So (Linda), Katie, of course thanks again. This might be a follow up question with kind of theme but maybe a slightly different focus. Of course unprecedented demand for some devices for a few months now. I'm wondering how it covers disruptions moving forward and shortfalls with high demand that currently exist. Does FDA intend for the guidance to be now and forward or what about situations where demand has been induced prior to issuance of the guidance?

(Linda Ricci): So we would want companies to consider the shortfall that they are having perhaps in their supply throughout the COVID experience. Obviously the guidance is new - and the legislation is about a month old. So moving forward we would want you to be thinking about what is still causing supply disruption and provide us the information on that, do the notification for that, understanding that this is only for COVID. The guidance document is only in response to COVID using the criteria that is outlined that Katie went through.

So for example we know that there's an incredible demand for pick your favorite medical device and there has been incredible demand and there still are back orders. We would want the manufacturer of those devices to provide the notification as indicated in this guidance.

(Michael Patrini): Okay thank you. That helps clarify. I appreciate it.

Coordinator: Thank you. And once again if you would like to ask a question at this time you can press star 1 on your phone and record your name when prompted. Our next question will come from (Harbanar). You may go ahead.

(Harbanar): Yes. Thank you for your time today. I have one question regarding timing on a response once we submit a question or a notification to the mailbox. What is the time frame for response through the FDA?

Linda Ricci: For a notification we will certainly let you know that we've received the notification and if there are any follow up questions that we have we'll get to those quickly. As for a particular time frame we currently don't have that and that may evolve depending on what the rest of the situation looks like with regards to that product type. As to questions we certainly want to get back to people as soon as possible understanding that the guidance published last Wednesday so that seven day mark is coming up. And if people have questions then we know we need to get them responses so that they can adequately notify us if they are obligated to do so.

(Harbanar): Thank you very much.

Coordinator: Our next question will come from (Mary Edwards). Your line is open.

(Mary Edwards): Thanks very much. I want to echo the thanks for this very clear presentation. Just one point I wanted to get a little bit of clarification, is - of the four criteria for who must notify it says life supporting or life sustaining or intended for use in emergency medical care or during surgery. That's a very broad range of devices. Is that devices being used during COVID-19 or any of the above?

Katie O'Callaghan: Any of the above.

(Mary Edwards): Okay great.

(Jessica Ritsick): And that language is in the statute at 506J.

(Mary Edwards): Right. It's just a very broad category so thank you for offering to give some clarification (unintelligible) to consider that would be a device (unintelligible) on for clarification on this, correct?

Katie O'Callaghan: Hello Mary, this is Katie. I think it may be worth taking this offline and then we can get into more of the specifics. But in general our interpretation of that language in the statute is that those types of devices, whether or not they are used for COVID-19, if COVID-19 impacts in the U.S. and globally are affecting the availability of those, then that would disrupt critical emergency or surgical medical care and that's something we also want to prevent and mitigate when possible.

(Mary Edwards): Great, that's a clear explanation. Thank you very much. And just one last question on that since a lot of us occasionally have devices we're working through some quality problems. And FDA has already been notified of those would you also want to be notified because that would be a disruption until the quality issue has been taken care of.

Katie O'Callaghan: Yes. And certainly the right and left hands will be communicating on this but we do still need that notification to fulfill 506J. I think once we get into full implementation we can connect some of those dots. But there is a section in the guidance in the example notification which includes as potential reasons

"requirements related to complying with the manufacturing practices" or "other regulatory delay" related issues. So you could use those to indicate that, and you don't need to reprovide any of the detailed information on those issues. We would be able to get that internally.

(Mary Edwards): So it's connecting the dots for you, that makes perfect sense. Thank you so much.

Coordinator: Thank you. Our next question comes from (Diane). Your line is open.

(Diane): Hello guys. Thanks for the time to take these questions. Just one point, it's clear that the notification is specific to devices that are cleared or approved by FDA. But just to confirm does the notification also cover devices or products that are introduced under emergency authorization?

(Jessica Ritsick): So you should refer to your specific EUA and the conditions of authorization of your EUA. And if you have questions about the EUA as it relates you can email the box.

(Diane): Okay thank you. So this would be in particular to NIOSH-approved respirators that aren't cleared as medical devices.

(Jessica Ritsick): Again we can't answer questions about specific devices on this webinar but we would encourage you to look at the conditions of authorizations of your EUA and if you have further questions, send us an email and we can help you figure it out.

(Diane): Okay thank you.

Coordinator: Thank you. Our next question will come from (Elizabeth George). Your line is

open.

(Elizabeth George): Sorry. I had to cancel that.

Coordinator: Thank you, the question will be withdrawn. We are showing no further questions at this time. I will now turn the call back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene here and we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH and our webpage at www.fda.gov/training/cdrhtolearn by Tuesday, May 19. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation.

As always we appreciate your feedback. Following the completion of today's webinar please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live webinar. Again thank you for participating and this concludes today's webinar.

Coordinator: Thank you. This does conclude today's conference. Thank you again for your participation. You may disconnect at this time.

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